DEPARTMENT OF HEALTH & HUMAN SERVICES

94712d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: CFN 2911677

May 12, 2004

Eugene A. Bugatto, President
California Shellfish Company, Inc.
420 Jefferson Street
San Francisco, California 94109

WARNING LETTER

Dear Mr. Bugatto:

On February 6, 9, 11, and 12, 2004, we inspected your seafood processing facility located at 420 Jefferson Street, San Francisco, California and found that you have serious deviations from Title 21 of the Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated histamine forming fish, e.g., tuna, Mahi Mahi, Escolar, and your refrigerated, ready-to-eat fish and fishery products, e.g., cooked unpasteurized Dungeness crabmeat vacuum packaged in hermetically sealed containers, vacuum packaged smoked salmon, and seafood salad, are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulation through links in FDA's home page at www.fda.gov. See attached handout on how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001. We listed the deviations on a Form FDA-483 and discussed them with Richard D. Amundsen, Vice President/General Manager, at the

conclusion of the inspection. We are enclosing a copy of the Form FDA 483 for your reference. Your serious HACCP deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b).

   (a) However, your firm does not have a HACCP plan for refrigerated, ready-to-eat unpasteurized crabmeat in hermetically sealed containers to control the food safety hazard of pathogen growth and toxin formation, specifically Clostridium botulinum toxin formation, as a result of time/temperature abuse during the receipt, storage, and distribution of the product.

   (b) Your firm also does not have a HACCP for refrigerated, ready-to-eat seafood salad to control the food safety hazard of pathogen growth and toxin formation as a result of time/temperature abuse during the receipt and storage of the product.

   (c) In addition, we suggest conducting a hazard analysis to determine if there is a potential for your histamine forming species to be consumed as raw. If so, we suggest that you amend your HACCP plan for "Fresh Tuna, Mahi Mahi, And Any Other Species with Possible Scombrotoxin Formation" to include pathogen growth and toxin formation as a potential food safety hazard for these products.

2. You must have a HACCP plan that, at a minimum, lists adequate monitoring procedures and frequencies for each critical control point, to comply with 21 CFR 123.6(c)(4).

   (a) Your firm's HACCP plan for "Fresh Tuna, Mahi Mahi, And Any Other Species with Possible Scombrotoxin Formation" lists a monitoring frequency at the Storage critical control point of "visual once per day" that is not

adequate to control histamine formation and pathogen growth and toxin formation.

(b) Your firm's HACCP plans for "Fresh Whole Cooked Dungeness Crab" and "Vacuum Packaged Cold Smoked Salmon Fresh/Frozen" list monitoring frequencies at the Storage critical control points of "visual once per day" that are not adequate to control pathogen growth and toxin formation.

For refrigerated storage, FDA recommends maintenance of the cooler at 40 F° or below with continuous monitoring of the temperature. You may chose to either monitor the cooler temperature by means of a continuous temperature data recorder or an alarm system or monitor the adequacy of ice or cooling media on the product at least twice a day.

(c) Your firm's HACCP plans for "Fresh Tuna, Mahi Mahi, And Any Other Species With Possible Scombrotoxin Formation," "Fresh Whole Cooked Dungeness Crab" and "Vacuum-Packaged Cold Smoked Salmon Fresh/Frozen" do not list adequate monitoring procedures at the Receiving critical control point to control pathogen growth and toxin formation. You indicate that temperature will be monitored on arrival, but do not specify if this is the temperature of the fish or temperature of the truck. If monitoring the temperature of the fish, you should indicate if this is surface temperature or internal and you should include a procedure that ensures that a representative number of containers in the lot are monitored at receiving. This will provide you with a better representation of the temperature(s) of your entire lot.

3. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plans for tuna, Mahi Mahi, and any other species with possible scombrotoxin formation, whole cooked Dungeness crab, and vacuum packaged cold smoked salmon contain a corrective action at the Receiving critical control point, "Reject," that does not

provide for correction of the cause of the deviation when the critical limit is exceeded. FDA recommends discontinuing use of the supplier or carrier until evidence is obtained that transportation practices have changed.

4. You must provide all mandatory records for official review and copying at reasonable times, to comply with 21 CFR 123.9(c). However, your firm was unable to provide the monitoring records at the Storage critical control point, of fish and fishery products covered by your HACCP plans, for production dates of January 5, 9, 12, 15, 16, 17, and 27, 2004.

5. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor key sanitation areas with sufficient frequency to ensure control:

   (a) Safety of water – FDA observed that the [redacted] containing ice used in seafood processing, has rust on the upper left side of the inner wall.

   (b) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments – On February 9, 2004, FDA observed a plastic ice shovel, was stored directly on the floor. FDA also observed during the inspection that the plastic cutting boards in the filleting room were heavily scored with greenish matter in between the scores.

6. You must maintain sanitation control records that, at a minimum, document the monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm is not documenting and maintaining records of daily sanitation monitoring.

You must immediately take appropriate steps to correct the violations. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.
Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to

correct these deviations. You may wish to include in your response documentation such as copies of the revised HACCP plan, HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the current Good Manufacturing Practices (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Barbara J. Cassens
District Director
San Francisco District

Enclosures

Form FDA 483
Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001

cc: Richard G. Amundsen, Vice President